



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/396,446	02/28/95	AHLUWALIA	G 00216/289001

15M1/0703

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EXAMINER

HARRISON, R

ART UNIT PAPER NUMBER

1501

DATE MAILED: 07/03/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/396,446

Applicant(s)
Ahluwalia et al.

Examiner
Robert H. Harrison

Group Art Unit
1501



☒ Responsive to communication(s) filed on 10/30/96 ; 12/23/96 and 3/6/97

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-74 is/are pending in the application.

Of the above, claim(s) 2-7, 9-20, 30-41, and 44-74 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 8, 21-29, 42, and 43 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8 and 10

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Receipt is hereby acknowledged of applicants' supplemental Information Disclosure Statement filed as of February 18, 1997 and applicants' amendment filed as of March 6, 1997.

Applicants' amendment to the claims filed with the response as of March 6, 1997 has not been entered because it is in direct conflict with the amendment Paper No. 7 filed with Certificate of Mailing as of December 17, 1996. Please note the previous amendment changed "inhibiting" to "reducing". The Examiner suggests the line 7 alteration of claim 66 in Paper No. 7 be changed from "reducing" to "reduce" in order to make sense. Please note that the amendment to claim 65 as set forth in Paper No. 6 with Certificate of Mail as of October 28, 1996 has not been entered since there is no claim 65 line 7 that appears and thus in such paper the amendment to claim 65 has not been entered at all. In any event, 65 does not contain the noted language.

The Examiner has enclosed a complete, Official PTO translation of the documents cited by the Examiner in the last Office action.

Applicant's election of mycophenolic acid as the non-steroidal suppressor of angiogenesis in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

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Claims 2-7, 9-20, 30-41 and 44-74 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected species. Election was made **without** traverse in Paper No. 11.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 8, 21-29, 42 and 43 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "reduce or reducing" in the claims is a relative term which renders the claims indefinite. The term "reduce or reducing" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree or degree of inhibition and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. See Amgen v. Chugai.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

As the cited reference provided with this Office action discloses mycophenolic acid contrary to being a hair growth inhibitor is a hair growth stimulating compound and thus one of ordinary skill in the art could not practice the invention as claimed. The Examiner notes applicant's specification appears to be a shotgun specification for a whole slew of compounds and mycophenolic acid has not been disclosed or specifically singled out for inhibition of hair growth but appears to be only a "paper example" of an active which is contemplated or will be obtained at some future date experimental data showing mycophenolic acid as useful in inhibiting hair growth. However, prophetic test systems are not considered to provide any basis for presuming that the claimed method of treating using mycophenolic acid is enabled in mammalian subjects or human hosts. It is well known and established that "law requires that disclosure in an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out to use it for themselves." In re Gardner et al., 166 USPQ 138 (CCPA 1970).

Claims 1, 8, 21-29, 42 and 43 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

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Applicants' arguments filed October 30, 1996 (Certificate of Mailing October 28, 1996) have been fully considered but they are not deemed to be persuasive.

Applicants traverse the first paragraph rejection under 35 U.S.C. § 112, arguing that applicants have provided enablement for their broad contribution and that applicants have furthermore sufficiently established through a representative testing of a substantial number of compounds which shows that reduction in hair growth is accomplished through inhibition of angiogenesis. Applicants further argue that reference L "seems to teach that mycophenolic acid can be used to "stimulate hair growth" but applicants seem to suggest that this is all that the reference teaches. These arguments are respectfully traversed since the testing shown in the instant specification is very specific to certain conditions, certain vehicles, concentrations and mode or method of application. Please note that the reference disclosure teaches topical application of mycophenolic acid which is the same mode of application that applicants are disclosing for their mycophenolic acid. Please note that the reference L teaches that indeed this topical formulation when applied to the skin achieves the exact opposite result and furthermore it is noted that applicants have provided no guidance as to how the result can be achieved since the reference disclosure encompasses the entire claimed formulations as well as mode of application and

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concentration since applicants are respectfully directed to their very own instant specification which states that the concentration of the compound can vary over a wide range. See page 8 last paragraph. The Examiner's position is that this very broad disclosure which applicants assert is their contribution is actually encompassed by the prior art which shows the exact opposite result and thus one of ordinary skill in the art could not achieve the invention without undue experimentation in order to select optimum conditions, suitable vehicle, mode of application and concentration in order to achieve reduction in hair growth. Any angiogenesis would be inherent in the reference L whether it be promoting or inhibiting angiogenesis. Furthermore, it is not seen how applicants' claimed invention overcomes the promotion of hair growth achieved by the patent reference L.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE

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ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert H. Harrison, whose telephone number is (703) 308-2422. The examiner can normally be reached on Monday-Friday from 9:30 A.M. to 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Lesmes, can be reached on (703) 308-2362. The fax telephone number for this Group Art Unit is (703) 305-5246.

Any inquiry of general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-2351.

RHH
RHHarrison:cdc

June 12, 1997



GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150